K093565

510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for **PleuraFlow Catheter System** 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Applicant: Clear Catheter Systems
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DEC - 3 2010

Date of Submission: November 17, 2009

Proprietary Name: PleuraFlow Catheter System

Common Name: Accessory to powered suction pump

Regulatory Class: II

Product Codes: OTK

Predicate Device(s): The primary predicate device used to demonstrate substantial equivalence is the Deutsch Anti-Blockage Wound Drain (K052286).

Device Description: The PleuraFlow Catheter System is comprised of a silicone drainage tube and a shuttle assembly and guide tube. The PleuraFlow drainage tube is 20 inches in length with graduated measurements in inches from the first side hole and will be available in standard sizes from 20Fr to 32Fr versions. There is a barium stripe in the tube to facilitate visualization. A connector at the proximal end of the device connects to a commercially available drainage system. Within the catheter is a tube clearance apparatus to facilitate clearing of the drainage tube. The tube clearance apparatus is composed of a PTFE-coated guide wire that has a loop set on

its distal end, bent at a 90-degree angle. The clearance apparatus is sized such that it cannot exit the end of the drainage tube or the side holes. The tube clearance apparatus is magnetically driven by an attached internal magnet coupled to an external magnet contained within the shuttle assembly.

Indication for use: The PleuraFlow Catheter is indicated for use as an adjunctive device during open surgical procedures in order to prevent fluid accumulation within the operative site after closure of the surgical wound.

The device is indicated for use in thoracic surgical procedures.

Substantial Equivalence: The PleuraFlow Catheter has the same or similar intended use, indications for use, principle of operation, and performance characteristics as predicate devices and is, therefore, substantially equivalent to the predicate devices.

Performance Data: The safety and effectiveness of the PleuraFlow Catheter has been demonstrated through data collected from clinical and nonclinical bench tests and analysis.

A total of 19 patients were enrolled in a User Preference Study. Patients undergoing cardiac surgery through a median sternotomy had two chest tubes placed in the midline; one standard chest tube and a PleuraFlow system. A study questionnaire was completed by the surgeon placing the chest tube, the nurse taking care of the patient prior to removal of the chest tube, and by the Physician Assistant or Resident who removed the chest tube. Findings from the study indicated that the time for assembly and ease of placement were acceptable to the surgeons, and that ease of use of the clearance mechanism and adequacy of chest tube clearance were acceptable to the ICU nurses. It was concluded that the device was helpful and easy to use, and performed as intended in the clinical setting.

Conclusion: The evaluation of the PleuraFlow Catheter does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Clear Catheter Systems
% M Squared Associates, Inc.
Ms. Monica Early Dougherty
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K093565
Trade/Device Name: PleuraFlow Catheter System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OTK
Dated: October 19, 2010
Received: October 20, 2010

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Dear Ms. Dougherty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: To be assigned K093565

Device Name: PleuraFlow Catheter System

Indications for Use: The PleuraFlow Catheter is indicated for use as an adjunctive device during open surgical procedures in order to prevent fluid accumulation within the operative site after closure of the surgical wound. The device is indicated for use in thoracic surgical procedures.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mkn

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093565